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EXAMINER
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BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/942,090

Applicant(s)

CASE ET AL.

Examiner

John S. Brusca

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 26-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-14 and 26-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of delivery of zinc finger proteins to cells by introduction of an expression vector, does not reasonably provide enablement for methods of delivery of zinc finger proteins to cells by introduction of exogenous zinc finger proteins to cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

- a) In order to practice the claimed invention one of skill in the art must regulate endogenous gene expression by delivery of a zinc finger protein to a cell. For the reasons

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discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The specification does not give specific guidance to deliver zinc finger proteins to cells and cause modulation of expression of an endogenous gene.

c) The specification does not provide working examples of delivery of zinc finger proteins to cells to cause modulation of expression of an endogenous gene.

d) The nature of the invention, regulation of gene expression by zinc finger proteins, is complex.

e) A search of the prior art does not show regulation of gene expression by delivery of zinc finger proteins to cells by any direct method. Beerli et al. and Liu et al. show that the teaching of the prior art at around the effective filing date of the instant application used exclusively expression vectors to introduce engineered zinc finger proteins into cells.

f) The skill of those in the art of molecular biology is high.

g) The prior art does not address the predictability of the full scope of the claimed invention.

h) The claims are broad in that they read on embodiments that are not supported by the instant specification or the prior art.

In order to practice the claimed invention, the skilled practitioner would first turn to the teachings of the instant specification to practice embodiments of the claimed invention in which zinc finger proteins are delivered as protein to cells. However, the instant specification does not provide specific guidance or working examples of such embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art also does not

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provide such guidance. Finally, said practitioner would turn to trial and error experimentation to practice the full scope of the claimed invention without guidance from the specification or the prior art. Such represents undue experimentation.

***Claim Rejections - 35 USC § 102***

3. For the purpose of examination the claims have been considered to be anticipated or obvious over prior art that anticipates or makes obvious each step of the claimed methods. The preamble is not considered to affect the scope of the claimed subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, and 4-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al.

The claims are drawn to a method of modulation of expression of a predetermined gene in a cell with a zinc finger protein and assaying the cell for a resulting change in phenotype. In some embodiments the gene expresses an mRNA and a protein. In some embodiments the zinc finger binds near the transcription start site or in a coding region of the gene. In some embodiments the zinc finger protein comprises a VP16 activation domain or a KRAB repression domain. In some embodiments the zinc finger comprises at least 3 zinc finger binding domains.

Liu et al. shows on pages 528-5529 and figure 4 modulation of expression of a target luciferase gene in a human cultured HeLa cell by introduction of an expression vector that expresses a six domain zinc finger protein linked alternatively to a VP16 activation domain or a

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Krab-A repression domain. The phenotype measured was expression at the protein level of the luciferase gene product, which inherently also measures transcription of the luciferase gene. The zinc finger protein binds to a site in the promoter region of the luciferase gene (see page 5526). Liu et al. discusses use of zinc finger proteins to modulate gene expression by binding within the coding region in the first column of page 5529.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. in view of Heix et al.

The claims are drawn to a method of modulation of expression of a predetermined gene in a cell with a zinc finger protein and assaying the cell for a resulting change in ribosomal RNA.

Liu et al. shows on pages 528-5529 and figure 4 modulation of expression of a target luciferase gene in a human cultured HeLa cell by introduction of an expression vector that expresses a zinc finger protein linked alternatively to a VP16 activation domain or a Krab-A repression domain. The phenotype measured was expression at the protein level of the luciferase gene product, which inherently also measures transcription of the luciferase gene. The zinc finger protein binds to a site in the promoter region of the luciferase gene (see page 5526). Liu et al. discusses use of zinc finger proteins to modulate gene expression by binding within the coding region in the first column of page 5529. Liu et al does not show modulation of expression of a ribosomal RNA gene.

Heix et al. shows in the abstract and throughout that HeLa cell ribosomal RNA gene expression is regulated with the cell cycle. Heix et al. shows that cell transcription factor activity is modulated to effect the regulation of the ribosomal RNA genes during the cell cycle.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Liu et al. to target ribosomal RNA genes to further study the effects of the cell cycle on ribosomal RNA genes.

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7. Claims 1, 13, 14, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. in view of Braselmann et al.

The claims are drawn to a method of modulation of expression of a predetermined gene in a cell with a zinc finger protein and assaying the cell for a resulting change in ribosomal RNA. In some embodiments the zinc finger is regulated by estradiol, and the cell is infected with a virus.

Liu et al. shows on pages 528-5529 and figure 4 modulation of expression of a target luciferase gene in a human cultured HeLa cell by introduction of an expression vector that expresses a zinc finger protein linked alternatively to a VP16 activation domain or a Krab-A repression domain. The phenotype measured was expression at the protein level of the luciferase gene product, which inherently also measures transcription of the luciferase gene. The zinc finger protein binds to a site in the promoter region of the luciferase gene (see page 5526). Liu et al. discusses use of zinc finger proteins to modulate gene expression by binding within the coding region in the first column of page 5529. Liu et al does not show regulation of a zinc finger protein by estradiol or infection of the cell with a virus.

Braselmann et al. shows in the abstract and throughout an estrogen regulated recombinant transcription factor which is fused to an estrogen regulated activation domain. Braselmann et al. shows that addition of estradiol activates expression of the targeted gene in figure 1. Braselmann et al. shows construction of a stable cell line Rat-1 Gal-ER that comprises the transcription factor gene by use of a viral expression vector on page 1658, allowing for additional selection for subsequent transfections with different vectors.



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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Liu et al. by use of the estradiol regulated activation domain of Braselmann et al. because Braselmann et al. shows that their system allows for inducible expression of cells by addition of estradiol at desired times. It would have been further obvious to use a viral infected cell because Braselmann et al. outlines a method of construction of cells comprising desired genes by use of viral vectors.

8. Claims 1 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. in view of Hagmann et al.

The claims are drawn to a method of modulation of expression of a predetermined gene in a cell with a zinc finger protein and assaying the cell for a resulting phenotypic change. In some embodiments the gene is a viral gene.

Liu et al. shows on pages 528-5529 and figure 4 modulation of expression of a target luciferase gene in a human cultured HeLa cell by introduction of an expression vector that expresses a zinc finger protein linked alternatively to a VP16 activation domain or a Krab-A repression domain. The phenotype measured was expression at the protein level of the luciferase gene product, which inherently also measures transcription of the luciferase gene. The zinc finger protein binds to a site in the promoter region of the luciferase gene (see page 5526). Liu et al. discusses use of zinc finger proteins to modulate gene expression by binding within the coding region in the first column of page 5529. Liu et al does not show regulation of a viral gene.

Hagmann et al. shows in the abstract and throughout that Herpes Simplex Virus (HSV) immediate early gene promoters are regulated by VP16 transcription factors. Hagmann et al. shows in figures 1-10 assays of activation of constructs in cells by VP16.

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Liu et al. to study the HSV gene constructs of Hagmann et al. to further study the effect of VP16 on HSV gene expression because Liu et al. shows that their zinc finger proteins allow localization of VP16 to sequences of choice.

9. Claims 1 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. in view of Burge et al.

The claims are drawn to a method of modulation of expression of a predetermined gene in a cell with a zinc finger protein and assaying the cell for a resulting phenotypic change. In some embodiments the predetermined gene is determined by a gene prediction algorithm.

Liu et al. shows on pages 528-5529 and figure 4 modulation of expression of a target luciferase gene in a human cultured HeLa cell by introduction of an expression vector that expresses a zinc finger protein linked alternatively to a VP16 activation domain or a Krab-A repression domain. The phenotype measured was expression at the protein level of the luciferase gene product, which inherently also measures transcription of the luciferase gene. The zinc finger protein binds to a site in the promoter region of the luciferase gene (see page 5526). Liu et al. discusses use of zinc finger proteins to modulate gene expression by binding within the coding region in the first column of page 5529. Liu et al does not show use of target genes determined by a gene prediction algorithm.

Burge et al. shows in the abstract and throughout an algorithm for prediction of genes in genomic sequences.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Liu et al. by use of the gene prediction algorithm of Burge et al. for the purpose of applying the method of Liu et al. to study other genes of interest.

10. Claims 1 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. in view of Bailey et al.

The claims are drawn to a method of modulation of expression of a predetermined gene in a cell with a zinc finger protein and assaying the cell for a resulting phenotypic change. In some embodiments the predetermined gene is determined by analysis of expressed sequence tags.

Liu et al. shows on pages 528-5529 and figure 4 modulation of expression of a target luciferase gene in a human cultured HeLa cell by introduction of an expression vector that expresses a zinc finger protein linked alternatively to a VP16 activation domain or a Krab-A repression domain. The phenotype measured was expression at the protein level of the luciferase gene product, which inherently also measures transcription of the luciferase gene. The zinc finger protein binds to a site in the promoter region of the luciferase gene (see page 5526). Liu et al. discusses use of zinc finger proteins to modulate gene expression by binding within the coding region in the first column of page 5529. Liu et al does not show determination of the target gene by analysis of expressed sequence tags.

Bailey et al. shows in the abstract and throughout a method of analysis of expressed sequence tags that allows for identification of corresponding genes in genomic sequences.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Liu et al. by use of the expressed sequence tag

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analysis method of Bailey et al. for the purpose of applying the method of Liu et al. to study other genes of interest.

11. Claims 1 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. in view of Gelfand et al.

The claims are drawn to a method of modulation of expression of a predetermined gene in a cell with a zinc finger protein and assaying the cell for a resulting phenotypic change. In some embodiments the predetermined gene is determined by similarity to cDNA sequences.

Liu et al. shows on pages 528-5529 and figure 4 modulation of expression of a target luciferase gene in a human cultured HeLa cell by introduction of an expression vector that expresses a zinc finger protein linked alternatively to a VP16 activation domain or a Krab-A repression domain. The phenotype measured was expression at the protein level of the luciferase gene product, which inherently also measures transcription of the luciferase gene. The zinc finger protein binds to a site in the promoter region of the luciferase gene (see page 5526). Liu et al. discusses use of zinc finger proteins to modulate gene expression by binding within the coding region in the first column of page 5529. Liu et al does not show determination of the target gene by similarity to cDNA sequences.

Gelfand et al. shows in the abstract and throughout a method of analysis of cDNA sequences that allows for identification of corresponding genes in genomic sequences.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Liu et al. by use of the expressed sequence tag analysis method of Gelfand et al. for the purpose of applying the method of Liu et al. to study other genes of interest.

***Double Patenting***

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of copending Application No. 09/941,450. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

16. Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In *re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In *re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized “that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim,” but that one can judge whether or not the invention

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claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

17. Claims 1, 5, 6, 8-14, and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 9, 11, 23-25, and 55 of U.S. Patent No. 6,599,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because some claims of U.S. Patent No. 6,599,692 are species of the instant rejected claims, and further because the specification of U.S. Patent No. 6,599,692 shows in column 10 that species of claim 9 include the small molecule RU486 for regulation of the zinc finger, and further shows in column 10 that species of activators and repressors of claim 11 include KRAB and VP16.

18. Claims 1, 4, and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, 12, and 13 of U.S. Patent No. 6,503,717. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent 6,503,717 are species of the instant rejected claims.

19. Claims 1, 9-14, and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 9-12, and 19 of copending Application No. 09/925,796. Although the conflicting claims are not identical, they are not patentably distinct from each other because some claims of copending Application No.

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09/925,796 are species of the instant rejected claims, and further because the specification of copending Application No. 09/925,796 shows in page 10 that species of claim 12 include the small molecule ecdysone for regulation of the zinc finger, and further shows in page 14 that species of activators and repressors of claims 9-11 include KRAB and VP16

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1-3, 5-14, and 26-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 and 26-30 of copending Application No. 09/941,450. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of copending Application No. 09/941,450 claims the zinc finger species of exogenous molecule of the copending claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

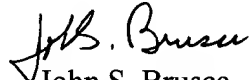
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00. On approximately 12 January 2004 Art Unit 1631 will move to the new USPTO Alexandria, VA facility. At that time the phone number of the examiner will change to (571) 272-0714. Phone calls to the previous phone number will be referred to the new phone number for 60 days after the move date.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb